Appln. No.: 10/687,344
Response dated December 5, 2005
Reply to Office Action of August 9, 2005

Amendments to the Specification

Please replace paragraph number 59 that begins on page 13 of the specification as filed with the following paragraph:

Figure 8 shows a functional diagram of an example of a seizure detection algorithm 800 that may be used. Generally, the seizure detection algorithm 800 is capable of detecting brain activity changes based on the spectral characteristics, intensity (ratio), spread, and duration of an electrical (EEG, ECoG, and/or EKG) signal 801 that is obtained from a set of electrodes. In the embodiment of external system 100, eight ECoG channels may be supported, although other embodiments may support a different number of channels. The analog EEG or ECoG data from the electrodes 101 are transformed to digital data with an A to D converter in the bedside device 107. In the hybrid system 1000, the A to D converter may be in the implantable device 953. A digital filter such as a finite impulse response (FIR) filter 803 is configured to estimate the power spectrum density characteristics of a set of electrical brain signals. A foreground determinator 805 associates a foreground value of the signals with a moving foreground interval of a predetermined time length (e.g., 2-seconds), which may be programmable. In the embodiment, foreground determinator 805 squares the value of each sample in the foreground interval and selects the median value. A background determinator 807 associates a background value with a moving background interval of predetermined time length (e.g., 30 minutes), which again may be programmable. At any point in time, the current foreground and background values are computed, respectively, from the foreground and background intervals that immediately precede that time point. Background determinator 807 squares the value of each sample in the background interval and selects the median value. The seizure detection algorithm 800 then processes the results of background determinator 807 through an "exponential forgetting" adjustor 809 that combines the results with previous results from background determinator 807 to produce a an exponentially-smoothed background value. A module 811 then divides the foreground value by the exponentially-smoothed background value to determine a ratio for each signal from each electrode in a selected electrode group. Module 811 also determines the largest ratio from the group of electrodes. The value of the largest ratio is then fed into a detection criterion module 813, which analyzes the sequence of largest ratios to determine when an event

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is detected. Output 814 from algorithm 800 includes notification that an event has occurred ("detection") as well as variables quantifying the event (e.g., ratio, extent of spread, and duration from all electrodes).

Please replace the paragraph number 96, beginning on page 28 of the specification as filed with the following paragraph:

A maximal amount of poor quality data that is tolerable may be qualified using different criterion. Poor quality data may be gauged by a signal power to noise power ratio (S/N) that is associated with neurological data. Also, poor quality data may be gauged by a fraction of the foreground window that contains a noisy signal. Typically, the foreground window is more vulnerable to noise than the background window since the foreground is determined over a shorter time duration. One may also consider different artifacts. Movement artifacts may be detected with accelerometers, in which corresponding outputs may be used to reduce or even cancel the movement artifacts. Other types of artifacts that may be ~~consider~~ considered include EKG artifacts and disconnection artifacts. EKG artifacts, when recorded from intracranial electrodes, are an indication of high impedance. Disconnection artifacts may be identified by stationary noise in one lead or a set of leads. The characteristics of a baseline that are associated with neurological data may assist in identifying a cause of poor quality data. For example, a flat line without a shift in the baseline and without noise may be indicative that an amplifier has been deactivated or has failed.

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Please replace the paragraph number 102, beginning on page 31 of the specification as filed with the following paragraph:

In step 2027, which comprises sub-steps 2029 and 2031, the correctness of electrode placement for seizure detection is verified. In sub-step 2029, the ITEO (investigator time of electrographic onset corresponding to time event 1903 in Figure 19) and the CBOT (clinical behavior onset time corresponding to time event 1907 in Figure 19) are provided to the medical device system. (In the embodiment, step 2027 is optional so that the clinician need not provide ITEO and CBOT to the medical device system.) In sub-step 2031, the medical device system determines if the ITEO did not occur after the CBOT. In the embodiment, the fact that the CBOT occurs before the ITEO is indicative that the selected electrodes are not sufficiently near the focus. In such a case, step 2032 determines whether to stop screening. If so, screening is ended in step 2034. Otherwise, step 2004 allows the physician-physcian to reposition subdural and/or DBS electrodes. The baseline algorithm monitoring sub-process 2003 is repeated.

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Please replace the paragraph number 104, beginning on page 31 of the specification as filed with the following paragraph:

If sub-step 2031 determines that the ITEO does not occur after the CBOT, step 2033 is executed, in which a localization accuracy and speed of detection are determined. Step 2033 comprises sub-steps 2035, 2037, and 2039. (In the embodiment, step 2033 is optional so that the clinician need not provide ITEO and CBOT to the medical device system.) In sub-step 2035, a spatial difference is determined between-a an ADT onset channel (i.e., the channel that the detection algorithm associates with the onset of the seizure) and-a an ITEO onset channel (i.e., the channel that is first associated with neurological activity as determined through visual analysis). While the ADT onset channel may be different than the ITEO onset channel, an event of the ADT onset channel and the ITEO onset channel being the same is indicative of localization accuracy. In sub-step 2037, the medical device system reports the spatial difference and whether the spatial difference exceeds a predetermined limit. The spatial difference exceeding the predetermined limit may be indicative that algorithm adaptation should be executed as in step 2041. In addition, in step 2039, a measure of the algorithm's detection delay is determined by calculating the difference between the times associated with the ADT and the ITEO. If the detection delay is sufficiently large, algorithm adaptation may be executed in step 2041.

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Please replace the paragraph number 174, beginning on page 57 of the specification as filed with the following paragraph:

Hardware and /or software blanking may be automatically applied based upon the results of applying signal quality control algorithms, such as those described ~~~~~~ ~~~~~~ ~~~~ ~~~~~~ sensor signals. Application of signal quality control may at anytime result in continuous hardware or software blanking of a particular sensor due to artifact. However, signal quality control algorithms may also be applied to any of the sensor channels to determine if the applied therapy (e.g., stimulation) is causing artifacts that require hardware or software blanking during and after application of the therapy. Those sensor channels determined not to be affected by the application of the treatment therapy do not need to be blanked, thus enhancing the ability of the system to monitor the patient. In addition, periodic checking of a sensor channel following a treatment pulse and applying signal quality algorithms can automatically determine the length of time needed for hardware and/or software blanking for that channel during future applications of the therapy. For example, a signal that is associated with an electrode in proximity of a stimulated electrode may be analyzed to have artifact characteristics, including during a time interval in which an artifact affects the signal. Alternatively, parameters of the therapy treatment may be adjusted within a range of values known to be therapeutic in an effort to reduce the effect on the signal quality of adjacent sensors. In this manner the medical device system can enhance ~~its~~ it's ability to collect data while providing treatment therapy.